

DO NOT ENTER: /S.C./

/Sara Clark/ 08/27/2010

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Reply to Office Action Dated April 1, 2010
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Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1-28. (Canceled)

29. (Currently amended) A method of promoting sleep initiation for a human who has difficulty falling asleep which comprises administering a sustained release form of melatonin in combination with at least one non-barbiturate and non-benzodiazepine hypnotic compound wherein said melatonin is administered in an amount effective to potentiate said compound's hypnotic effect and enhance said human's daytime vigilance ~~and said melatonin is administered in a sustained release form.~~

30. (Previously presented) The method of claim 29, in which said melatonin and said hypnotic compound are administered in a single pharmaceutical formulation.

31. (Previously presented) The method of claim 30, which is further characterized by at least one of the following features:

- (a) said hypnotics are GABA-A receptor modulators;
- (b) said hypnotics are compounds which include a fused-ring system containing ring nitrogen;
- (c) said formulation comprises at least one carrier, diluent, coating or adjuvant;
- (d) said formulation is in unit dosage form; and

(e) said at least one hypnotic compound is present in said medicament and in an amount which, if administered in absence of melatonin, would be a sub-therapeutic amount.

32. (Previously presented) The method of claim 31, wherein said formulation includes at least one acrylic resin.

33. (Previously presented) The method of claim 32, wherein said formulation is further adapted for regular release of said at least one compound.

34. (Previously presented) The method of claim 29, 30 or 31, wherein said at least one compound comprises a bicyclic fused ring system.

35. (Previously presented) The method of claim 34, wherein said bicyclic fused ring system includes at least two ring nitrogen atoms.

36. (Previously presented) The method of claim 35, wherein said bicyclic ring system comprises a pyrazolo[1,5-a]pyrimidine, imidazo[1,2,-a]pyridine, pyrrolo[3,4-b]pyrazine or triazolo[4,3-a]-pyridine skeleton.

37. (Previously presented) The method of claim 36, wherein said at least one hypnotic compound is selected from the group consisting of zaleplon, zolpidem, zopiclone and trazodone.

38-47. (Cancelled)

48. (Previously presented) The method of claim 29, wherein said hypnotic compound is zolpidem.

49. (Previously presented) The method of claim 29, wherein said hypnotic compound is administered in a sub-therapeutic dose.